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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/663,111

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Charles J. Davidson

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CROMPTON, SEAGER & TUFTE, LLC

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SUITE 800

MINNEAPOLIS, MN 55403-2420

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/663,111	Applicant(s) DAVIDSON ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,11-19,42-48,50-52,54-70 and 72-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,8,11-19,42-48,50-52,54-70 and 72-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 8, 11-19, 42-48, 72, and 74 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new language of the "wherein" clause lacks original support. The Applicant failed to point out support for the amendments and copending applications as requested; see the "Conclusion" section of the Office action mailed October 31, 2009; failure to respond to this request may result in the response being held non-responsive in the future. In particular, all the options suggested by the amended "wherein" clause of base claims 1 and 72 cannot be found in that "at least one of the first catheter radiopaque marker and the first side

member radiopaque marker . . . " appears to not have been contemplated in full because separation of all the markers is suggested.

Claim 1, 7, 8, 11-19, 42-48, 72, and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for separation of markers nearer the ends of the catheters, does not reasonably provide enablement for separation of all the markers as suggested by the present claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Accordingly, the Examiner asserts that as an alternative to the above rejection, the claims may merely lack enablement for certain configurations suggested by the amended claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, 8, 12, 13, 15-19, 42-48, 50-52, 55, 56, 59-70, and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al (US 6,165,195) in view of Ryan et al (US 6,576,009) or Shakhovich (US 5,669,924) or Goicoechea et al (US 5,609,627). Wilson meets the claim language where **(a)** the catheter as claimed is catheter (50) of Wilson (see Figure 12L and column 16, line 35 et seq.), **(b)** the side member as claimed is lumen (55A), **(c)** the free end as claimed is the angled portion

(55B), **(d)** the indicator as claimed is marker(s) (see column 17, line 64 to column 18, line 14), and **(e)** the side hole as claimed is aperture (25). Wilson places radiopaque markers on various elements but not multiple markers on each element as claimed. However, Ryan (see Figure 7 to 8B and column 11, line 34 et seq.) or Shaknovich (see column 12, lines 42-47) or Goicoechea (see Figure 4a and column 10, lines 53-64) teaches that it was known to put multiple markers on the same element in order to determine orientation thereof. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to an ordinary artisan to put more than one marker on each element of Wilson for the same reasons that the secondary references did the same.

With regard to the language that requires the catheter extend to a position distal of the side hole in the stent, the Examiner asserts that distal is a relative term and that the angled portion (55B) extends distally from the hole (25) to the extent required because it extends away farther down the vasculature with respect to the heart.

With regard to claim 8, the Applicant is directed to Figures 14 to 19F and the corresponding descriptions thereof.

Claims 1, 7, 8, 11, 12, 13, 15-19, 42-48, 50-52, 54, 55, 56, 58-70, and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson, Ryan, Shaknovich, and Goicoechea as applied to claim 1 above, and further in view of Dibie (WO 96/34580).

Regarding claims 11, 54, and 58, Wilson fails to disclose a balloon on the end of the lumen (55B) as required by the claim language. However, Dibie (see the front page thereof) teaches that it was known to put balloons on the ends of similar side members

in order to expand side stents. Therefore, it is the Examiner's position that it would have been obvious to do the same to the Wilson device in order to apply a side stent in one step or for the reasons that Dibie does the same.

With regard to claims 1, 7, 8, 12, 13, 15-19, 42-48, 50-52, 55, 56, 59-70, and 72-74, the Examiner has interpreted "extend . . . to a position distally of the side hole in the stent" more narrowly to require the end marker to be immediately adjacent to a distal end of the stent. However, Dibie suggests that such a configuration would have been obvious to an ordinary artisan; see Figures 5 and 11. Therefore, the Examiner asserts that it would have been *prima facie* obvious to make the Wilson catheter longer and to extend along the stent side to the end for the same reasons that Wilson utilizes such a configuration.

Claims 14 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson, Ryan, Shaknovich, and Goicoechea as applied to claim 1 above, and further in view of Davila et al (US 5,851,464). Wilson fails to disclose the use of pebax and graphite in the catheters. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to make the catheter of Wilson out of pebax and graphite for the same reasons that Davila did the same or in order to promote sliding between the catheter and guidewire.

Response to Arguments

Applicant's arguments filed January 30, 2009 have been fully considered but they are not persuasive.

On pages 11-17 of the response, the Applicant argues that it would not have been obvious to have the distal portion of the side member extend to a position distal of the side hole. This new language has been addressed by the Examiner within the rejections themselves. Therefore, the rationale utilized therein is incorporated herein by reference thereto.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774